REGULATORY TIPS AND UPDATES– DID YOU KNOW?

UNIVERSITY OF Cincinnati

IM Regulatory Newsletter

In this issue:

How to be prepared for a HRPP Audit of your Investigator-Initiated study.

Complete regulatory records should be kept for Investigator-Initiated studies, just as they would for sponsored studies. What does that mean?

Investigator-Initiated studies can be tricky in terms of regulatory records, and easily neglected. This is likely because there is no external monitoring holding investigators accountable.

However, UC's Human Research Protection Program (HRPP office) may audit your Investigator-Initiated study at any time. Please review this list of items that should be maintained for the duration of your study, and easily provided should you be audited:

Important Study Staff Documents to Maintain -

- Delegation of Authority (DOA) Log
  - This is a living document and should be kept current at all times.
- Training documents
  - All staff on the DOA should have documented training on all versions of the protocol from start to completion of a study.
- COIs for all key staff if your study has any type of funding
  - COIs should be completed with every Continuing Review
- Current credentials (CVs, Licenses and CITI training records) on all staff listed on your delegation log

FDA Documentation (if applicable) -

- Form 1571s and 1572s (all versions)
- Form 482 / 483
- All FDA related documents including submissions, acknowledgments, and correspondence

Types of Study Documentation –

A regulatory file should be kept on your Investigator-Initiated Study:

- For studies opened prior to July 2019, a paper-binder is acceptable.
- Studies that began after July 2019 should be in Complion unless otherwise indicated.

Study Binder Contents should include:

- All versions of the protocol
- All versions of IRB approved Informed Consents (if applicable)
- All versions of the IB (if applicable)
- All protocol deviations
- Any site monitoring logs (if applicable)
- DSMB reports (if applicable)
- IRB Submission reports
- IRB Approval letters
- IRB Correspondence

Separate: subject records/binders should be kept separate from your regulatory files: (do not keep your patient records that include PHI with your regulatory documents)

- CRFs/data collection forms and source documents, including medical file for all participants enrolled in your study.
- All SAE reports (if applicable)
- Screening/enrollment logs
- Telephone logs with participants (if applicable)
- All Signed Informed Consents
- Any other pertinent study documents

TIP!: UC Health Approval is still required for all Investigator-Initiated Studies

If you have any questions, please do not hesitate to reach out to:

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